REMARKS

The foregoing amendments and the following remarks are responsive to the June 23, 2008 Office Action (the "Office Action").

While Applicants respectfully disagree with the Examiner's rejections, to advance prosecution, Applicants have amended one or more claims. Applicants are not acquiescing to the rejections and reserve the right to pursue in a related application claims at least as broad as the amended claims prior to the amendments set forth herein. Applicants respectfully request the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following comments.

Claim Rejections – 35 U.S.C. 112 – Claims 7 and 8:

The Examiner rejected Claims 7 and 8 under 35 U.S.C. 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have amended Claims 7 and 8 to address Examiner's rejection.

Double Patenting:

Claims 1-4 and 10 stand rejected on the ground of non-statutory obviousness type double patenting over Claims 1-4 and 14 of U.S. Patent Application No. 11/577,642 (the '642 Application). According to the Office Action, "a nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s)." Applicants respectfully disagree with Examiner's statement in the Office Action that the "conflicting claims ... are not patentably distinct from each other because the '642 Application claims every material limitation of the instant invention."

Claim 1 of the instant application has at least two limitations that are not set forth in any of the presently pending claims in the '642 Application. In particular, Claim 1 of the instant application has (1) a means for bleeding the fluid flow path, and (2) a fluid recirculation tube for directing cleansed fluid from the means for fluid cleansing back into the inlet pipe so that

nutrients, molecules, factors, and/or other components from the wound exudate that aid in proliferation or that are favorable to the wound healing process are returned to the wound. Neither of these two limitations is present in any of the current claims in the '642 Application and Applicants submit that neither of these two limitations, in combination with the other recited claim limitations, would have been obvious based on the claim limitations recited in Claims 1-4 and 14 of the '642 Application. Therefore, Claim 1 of the instant application is not anticipated by, or obvious over, any of the claims currently in the '642 Application.

For at least these reasons, Applicants respectfully submit that Claim 1 and dependent Claims 2-4 and 10 are patentably distinct over Claims 1-4 and 14 of the '642 application. Therefore, Applicants respectfully request the Examiner to withdraw the obviousness-type double patenting rejection.

Claim Rejections – 35 U.S.C. 102(a) – Claims 1-5, 9, and 10:

The Examiner rejected Claims 1-5, 9, and 10 under 35 U.S.C. 102(a) as being anticipated by International Application Publication No. WO 02/092783 ("Orgill"). Respectfully stated, none of Claims 1-5, 9, and 10 is anticipated by Orgill under 35 U.S.C. 102(a) because Orgill does not show every element of each claim arranged as in each claim, before or after the above amendments. *See* MPEP §2131. Moreover, as discussed below, Orgill also does not render any of these claims obvious.

Regarding Applicants' amended Claim 1, respectfully stated, Orgill does not disclose or suggest, inter alia, an apparatus for aspirating, irrigating, and/or cleansing wounds, comprising a fluid flow path (comprising a conformable wound dressing, at least one inlet pipe communicating with at least a fluid reservoir, and at least one outlet pipe), a means for fluid cleansing in direct or indirect communication at least with the outlet pipe configured to retain in the cleansed fluid nutrients, molecules, factors, and/or other components from the wound exudate that aid in proliferation or that are favorable to the wound healing, a fluid recirculation tube for directing cleansed fluid from the means for fluid cleansing into the inlet pipe so that nutrients, molecules, factors, and/or other components from the wound exudate that aid in proliferation or that are favorable to the wound healing process are returned to the wound, a biodegradable scaffold located under the backing layer and configured to be placed in contact with a wound bed in use, a

device for moving fluid through at least the wound dressing and means for fluid cleansing, and a means for bleeding the fluid flow path, the apparatus being configured such that fluid can be supplied to fill the fluid flow path from the fluid reservoir and such that at least a portion of the fluid flowing through the outlet pipe can be recirculated via the fluid recirculation tube through the fluid flow path, as set forth in Claim 1.

In short, Applicants submit that Orgill does not disclose or suggest, inter alia, a means for bleeding the fluid flow path. Applicants understand the Office Action to state that the means for bleeding the flowpath is anticipated by Orgill because "at any portion of the sealed system, the seal to atmosphere can be broken/vented manually/by hand." Applicant has amended Claim 1 to recite that that the means for bleeding the fluid flow path bleeds fluid from the recirculation tube. Moreover, Applicant notes that the language "means for bleeding the fluid flow path" is a means-plus-function limitation, and therefore should be construed to cover the corresponding structure as described in the specification and equivalents thereof. Applicants' specification states that the "[means for bleeding the flow path] may be a regulator, such as a valve or other control device, e.g. a T-valve that is turned to switch between bleed and recirculation, for bleeding fluids from the apparatus, e.g. to a waste reservoir, such as a collection bag." *See* Application (WO 2005/046762), p. 23, lines 8-10.

For Claim 1, the means for bleeding the flow path is a mechanism that permits the fluid within the flow path to be regulated such that, inter alia, a portion of the fluid can be bled (such as to a waste reservoir) and a portion of the fluid can be recirculated through the flowpath. Respectfully stated, breaking any portion of the sealed system would cause the fluid in the system to leak uncontrollably and would not result in any of the fluid being (1) diverted to a waste reservoir, or (2) recirculated to the flow path. For these reasons, Applicants respectfully submit that Orgill does not disclose or suggest a means for bleeding the flowpath.

Additionally, because the wound may be in a highly exuding state, this may cause a positive change in the balance of fluid in recirculation. As such, Claim 1 provides a means for bleeding the fluid flow path to bleed fluid from the recirculation tube in order to maintain the proper amount of fluid in the flow path and, hence, regulate the pressure within the flowpath. Orgill, by contrast, neither contemplates nor appreciates the desirability of the combination of

features of Applicants' Claim 1, and particularly fails to teach or suggest the use of a means for bleeding the fluid flow path as set forth in Claim 1.

Moreover, Claim 1 further recites a fluid recirculation tube for directing cleansed fluid from the means for fluid cleansing back into the inlet pipe so that nutrients, molecules, factors, and/or other components from the wound exudate that aid in proliferation or that are favorable to the wound healing process are returned to the wound. As described in non-limiting embodiments of Applicant's specification, cleansed, recirculated fluid (and/or new irrigation fluid) containing nutrients, molecules, factors, and/or other components from the wound exudate that aid in proliferation or that are favorable to the wound healing process can be passed to the wound bed that, when combined with the biodegradable scaffold, provides enhanced benefits. "Such physiologically active components of the exudate that are beneficial to wound healing may be e.g. [] enzymes, nutrients for wound cells to aid proliferation, and other molecules that are beneficially involved in wound healing, such as growth factors, enzymes and other proteins and derivatives." *See* Application (WO 2005/046762), p. 27, lines 1-4. "Circulating wound fluid aids in movement of [] biological signaling molecules involved in wound healing to locations in the wound bed and are favorable to wound healing process and/or to cells that would not otherwise be exposed to them ..." *See* Application (WO 2005/046762), p. 27, lines 10-13.

Circulating beneficial components of the wound exudate back to the wound dressing and, in particular to the scaffold, such as set forth in the Applicants' Claim 1, is one example where circulation of the wound fluid has a synergistic benefit when used in a system that also has a scaffold. This is in part because recirculation of the beneficial components of the wound exudate allows the beneficial components from the exudate (such as the cells, platelets, growth factors, amino acids, glucose, etc.) to be returned to the wound bed and transported to portions of the scaffold that may otherwise be isolated from such beneficial components without recirculation. *See* Application (WO 2005/046762), p. 27, lines 18-21, stating as follows. "This is especially the case in those embodiments of the apparatus [] where there is an inlet or outlet manifold that delivers or collects the fluid directly from the scaffold over an extended area." Tissue that proliferates into the scaffolding typically has insufficient vascular properties to transport the growth factors and other beneficial components to the cells growing within the scaffolding. For

this reason, the efficacy of the implanted scaffold can depend on the provision of components beneficial to wound healing as well as the control of components deleterious to would healing.

Therefore, cleansing and hence removing the deleterious components from the exudate and then recirculating and dispersing the beneficial components to the cells proliferating within the scaffolding provides benefits not contemplated by the embodiments disclosed in Orgill. Moreover, Orgill's micropore filter would remove *beneficial solid components* from the wound exudate (such as cells, cell fragments, and/or platelets, etc.) so that such beneficial solid components are not returned to the wound where such components can promote wound healing.

Regarding Claims 2-5, 9, and 10, respectfully stated, these claims are not anticipated or suggested by Orgill for at least the same reasons as for the claim or claims from which they depend, and also because they each recite further patentable distinctions. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of Claims 1-5, 9, and 10 in view of the amendments and clarifications listed above.

New Claims Have Been Added:

New Claims 11-35 have been added. These claims are fully supported by the application as filed such that no new matter has been introduced by this Amendment. Regarding the art references cited in the Office Action, Applicants submit that Claims 11-35 are not anticipated or suggested by, or unpatentable over, the cited references for at least the same reasons as for Claims 1-10, and also because they each recite further patentable distinctions.

For example, in addition to the distinctions discussed above, with respect to Claim 13, Applicants submit that Orgill does not teach, suggest, or even contemplate, inter alia, a fluid cleansing mechanism configured to at least reduce the amount of *fluid soluble* deleterious components in the fluid that flows out of the dressing.

Applicants submit that the micropore filter disclosed in Orgill is not capable of distinguishing between beneficial and deleterious compounds but, rather, is only capable of removing *solid materials* (but, importantly, not soluble materials) that have a size greater than the pore size of the filter. Because certain deleterious components are typically present in the exudate in *soluble* as well as solid form, Applicants submit that Orgill's filter is not configured to

at least *reduce the amount of fluid soluble deleterious components in the fluid* that flows out of the dressing, as is stated in Claim 13, as is required for Orgill to anticipate Claim 1.

Moreover, as with Claim 1 above, Claim 13 further recites a fluid recirculation tube for directing cleansed fluid from the fluid cleansing mechanism into the inlet pipe so that nutrients, molecules, factors, and/or other components from the wound exudate that aid in proliferation or that are favorable to the wound healing process are returned to the wound. As stated above, Orgill's micropore filter would remove beneficial solid components from the wound exudate (such as cells, cell fragments, and platelets, etc.) so that such beneficial solid components are not returned to the dressing where such components can promote wound healing. Therefore, cleansing and hence removing the soluble deleterious components from the exudate and then recirculating and dispersing the beneficial components (including beneficial solid components) to the cells proliferating within the scaffolding provides benefits not achieved, taught, or even contemplated by the embodiments disclosed in Orgill.

With respect to Claim 23, for the reasons discussed above and because Orgill's filter would remove cells, platelets, and/or other beneficial solid components from the wound exudate, Applicants submit that Orgill does not teach, suggest, or even contemplate, inter alia, cleansing the fluid that flows out of the wound dressing to reduce the amount of deleterious components in the fluid that flows out of the dressing *without substantially reducing the amount of the components in the fluid that flows out of the dressing that are beneficial to wound healing*, in combination with recirculating at least a portion of the fluid that flows out of the wound dressing back to the dressing after being cleansed *so that nutrients, molecules, factors, and/or other components from the wound exudate that aid in proliferation or that are favorable to the wound healing process* are returned to the wound.

Allowable Subject Matter:

Applicants note with appreciation Examiner's indication of allowability of the invention set forth in Claim 6 if Claim 6 is rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 6 has been rewritten in independent form as suggested by the Examiner.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Oct. 23, 2008

By: Kregg Koch

Kregg A. Koch
Registration No. 63,035
Attorney of Record
Customer No. 20995
(949) 760-0404

5837430_6